NOV - 2 2011

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
K111345

See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, and decorative)

I. Submitter Information

510(k) Owner:	The See Clear Company, Inc. 4995 Buford HWY Ste 102 Norcross, GA 30071, USA
Contact Person:	Ms. DaYoung Kim 719-761-7603 (office) 866-504-8066 (fax)
Consultant & Submission Correspondent:	Kevin Randall, Principal Consultant ComplianceAcuity, Inc. 16576 W. 53rd Way Golden, CO 80403 (303) 828-0844 (direct) (303) 828-0835 (fax) Email: info@complianceacuity.com
Date Summary Prepared:	October 25, 2011

II. Name of Device

* Trade Name: See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, decorative). Clear and decorative designs may be distributed under unique or "private label" trade names such as See Clear, See Clear Color, and Fierce Contact Lenses.
* Common Name: Daily Wear Soft Contact Lens
* Classification Name: Lenses, Soft Contact, Daily Wear
* USAN (generic name): Polymacon

III. Predicate Devices

In conformance with Section 510(k) of the Food, Drug and Cosmetic Act, The See Clear Company hereby submits this notification of our intent to manufacture and place into interstate commerce the See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear. The predicate device to which substantial equivalence is being claimed is identified in the matrix below:

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Subject Device	Predicate Device(s)
See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, and decorative)	MiGwang Comfort 38 (polymacon) Spherical Soft Contact Lens for Daily Wear (clear, tinted, and cosmetic) (K051477)

A comparison of similarities and differences between the See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear, and the legally marketed predicate lens has been tabulated in the Substantial Equivalence Comparison Matrix exhibited below:

Comparison Element	Subject Lens:	Predicate:
Identification	See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, decorative)	MiGwang Comfort 38 (polymacon) Spherical Soft Contact Lens for Daily Wear (clear, tinted, and cosmetic)
Manufacturer	The See Clear Company	MiGwang Contact Lens Co. Ltd.
510(k) Number	K111345	K051477
Intended Use	Daily wear correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses are available clear, or with a visibility-handling tint, or with a decorative tint intended to enhance or alter the apparent color of the eye for day-to-day cosmetic or occasional decorative purposes.	Daily wear correction of visual acuity in aphakic or not aphakic person with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.
Production Method	Molded Base Curve Surfaces with Lathe-Cut Front Curve Surfaces	Molded Base Curve Surfaces with Lathe-Cut Front Curve Surfaces
Hydrophilic Material / USAN	polymacon	polymacon
Water Content	38 % +/- 2%	38 % +/- 2%
Index of Refraction	1.43	1.43

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See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, and decorative)

Comparison Element	Subject Lens:	Predicate:
Light Transmittance	>90%	>90%
Oxygen Permeability	11.92 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method)	9.77 X 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method)
Specific Gravity	1.184	1.165
Tensile Strength @ Break (MPa)	0.55	0.559
Modulus of Elasticity (MPa)	0.78	0.728
Elongation @ Break (%)	99.9	127.36
Breaking Force (Nmm)	0.66	0.66

The See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear is substantially equivalent to the predicate device in terms of the following key areas:

- Same Indications for Use
- Same Contraindications
- Same Design concepts
- Same "Listed" Color Additives
- Same Production Method used in the fabrication of the lens
- Same Lens Function
- Same Warnings
- Same Precautions
- Same polymer (polymacon)
- Similar Parameters being offered

It is the conviction of The See Clear Company that the information and data submitted in this 510(k) substantiate our ability to manufacture a contact lens with a safety and effectiveness profile that is substantially equivalent to the predicate device, and *does not raise* different questions of safety and effectiveness. When placed on the human eye the See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear performs the same function as the legally marketed predicate device identified herein.

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See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, and decorative)

IV. Device Description & Technological Characteristics

The See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, and decorative) are hemispherical shells with molded spherical base curves and lathe-cut front surfaces and are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves that conform to the shape of the radius of the cornea and center over the apex of the cornea to provide correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes.

The non-ionic lens material, **polymacon**, is a hydrophilic copolymer of 2-hydroxyethyl methacrylate (2-HEMA) cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. It consists of consists of 62% polymacon and 38% water by weight when immersed in normal buffered saline solution. The lenses are available clear, or with a visibility-handling tint, or with a decorative tint intended to enhance or alter the apparent color of the eye for day-to-day cosmetic or occasional theatrical purposes. These decorative designs may be distributed under a unique or "private label" trade name such as See Clear, See Clear Color, and Fierce Contact Lenses. Lenses are tinted only with FDA-approved ("listed") listed color additives for which FDA has previously reviewed the toxicology / biocompatibility profiles. Tinted lenses contain only the amount of color additive needed to accomplish the intended decorative effect.

In the dry (unhydrated) state the lens is machined and polished. In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. When placed on the cornea, the See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear acts as a refracting medium to focus light rays on the retina.

The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped, however it will return to its proper configuration when completely rehydrated in the proper storage solution.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 38% water by weight. The physical properties of these **polymacon** lenses are:

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See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, and decorative)

Refractive Index	1.43 (hydrated)
Light Transmission (clear)	greater than 90% T
Light Transmission (tinted)	greater than 80% T
Water Content	38 % +/- 2%
Specific Gravity	1.184 (hydrated)
Oxygen Permeability	11.92×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

V. Intended Use

The **See Clear Spherical Soft Contact Lenses (polymacon) for Daily Wear** are indicated for the correction of visual acuity in aphakic and not aphakic person with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Eye care practitioners may prescribe the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

VI. Non-Clinical Performance Data

To support the substantial equivalence claim made herein, a combination of non-clinical analysis and testing has been performed as detailed in this Premarket Notification. This includes:

• Chemical composition of finished lenses	• Color and light transmittance
• Purity of initial monomers	• Refractive index
• Shelf Life	• Water content
• Leachability of Residual Monomers	• Oxygen permeability
• Leachability of Color Additives	• Specific gravity
• Biocompatibility testing	• Mechanical Testing
• Sterilization Validation	

END OF 510(k) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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The See Clear Company
c/o Mr. Kevin Randall
Official Correspondent
Compliance Acuity
16576 W. 53rd Way
Golden, CO 80403

Re: K111345
Trade/Device Name: See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, and decorative)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: September 30, 2011
Received: October 4, 2011

Dear Mr. Randall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111345

Indications for Use

510(k) Number (if known): K111345

Device Name:

See Clear Spherical Soft Contact Lens (polymacon) for Daily Wear (clear, visibility-tinted, and decorative)

Indications For Use:

The **See Clear Spherical Soft Contact Lenses (polymacon) for Daily Wear** are indicated for the correction of visual acuity in aphakic and not aphakic person with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of .50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.

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Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Rollog
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111345